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(71) Applicant (*for all designated States except US*): SOMANETICS CORPORATION [US/US]; 1653 East Maple Road, Troy, MI 48083–4208 (US).

(72) Inventors; and
(75) Inventors/Applicants (*for US only*): SCHEUING, Richard, S. [US/US]; 441 Farmridge Court, Rochester Hills, MI 48307 (US). YOUNGBLOOD, James, H. [US/US]; 333 Hillwood, White Lake, MI 48383 (US).

(74) Agent: CARRIER, Robert, J.; Price, Heneveld, Cooper, DeWitt & Litton, 695 Kenmoor, S.E., P.O. Box 2567, Grand Rapids, MI 49501 (US).

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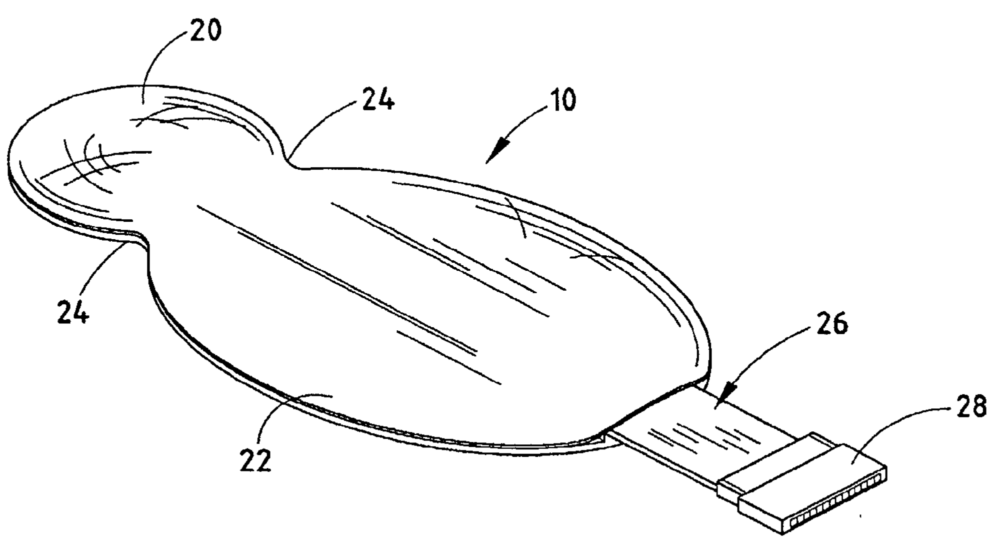

(57) Abstract

This invention is a small, and lightweight spectrophotometric sensor which is particularly, but not necessarily exclusively, useful in cerebral oximetry incorporates a flex circuit (26) having surface mounted electro–optical components that are electrically coupled to conductive traces carried on the flex circuit. At least some such components have an integrally attached rigid, and opaque light passage defining structure which may include a collar–like member, and is preferably a molded element that is "overmolded" upon the electro–optical component. The flex circuit includes a thin elongated member which includes alternate coatings of conductive, and non–conductive material over the conductive traces to provide electrical insulation, and electromagnetic shielding. The conductive traces are connected to short electrical leads extending outwardly from the sensor for only a brief distance, terminated by a manually connectable, and disconnected connector member. The flex circuit is mounted on a soft, thin, opaque, foam body (12), and covered by a thin protective layer (16).

PATIENT SENSOR FOR CLINICAL SPECTROPHOTOMETRIC APPARATUS

BACKGROUND OF THE INVENTION

This invention relates generally to spectrophotometric devices and apparatus, particularly those used for medical purposes, for non-invasively monitoring or otherwise obtaining data from patients or other test subjects by passing selected light spectra through portions of the patient anatomy and monitoring the resulting light to obtain data based on spectrally related absorption by particular biologic substances which reveal internal physiological conditions.

More particularly, the invention relates to the sensors which are used to produce and administer the selected light spectra, and to detect the resultant light emanating from the test subject after it has transmissed the anatomical portion under test. Still more particularly, the invention pertains to sensors of this basic nature which comprise soft, light-weight, compliant members which carry the necessary electro-optical components (*e.g.*, emitters, detectors, and the like) and which are applied to a selected area or location on the patient/test subject in a manner which holds the electro-optical components in their desired positions relative to the patient/test subject, *e.g.*, normally in direct light-tight contact with the skin.

Many different versions and types of such sensors have been developed over the past decade or thereabouts, during which medically-related spectrophotometric devices have been developed and have gained increasing usage in hospitals and other such clinical locations. Many or most such previously developed sensors pertain to pulse oximeters, which are used to obtain a measure of arterial hemoglobin oxygen saturation on an ongoing, in vivo basis, most typically by attaching the sensor to the patient's finger, ear lobe, or the like. Other types of such sensors for using the broad underlying spectrophotometric principals to accomplish various other novel results have also been developed or proposed previously, particularly by Somanetics Corporation of Troy Michigan, the Applicant herein, which has developed a non-invasive spectrophotometric cerebral oximeter. That device operates on a non-pulsatile basis to compute oxygen saturation in the brain by mounting one or more sensors on the forehead and using selected light wavelengths in the near infrared/red bandwidth to transmiss brain tissue underlying the forehead and detect spectral absorption of the selected light wavelengths by the blood present in that area. In this regard, reference is made to Applicant's prior

U.S. Patent Nos. 5,795,292, 5,697,367, 5,584,296, 5,482,034, 5,465,714, and 5,217,013, relating to various aspects of this development and its associated apparatus.

Due to the emphasis on sanitation rigorously followed in hospitals and other such health facilities, the standard operating protocol is the utilization of single-use devices and equipment which comes in a sterilized container and is thrown away after use, or even after the container is opened. That same protocol has been followed in the use of spectrophotometric devices such as pulse oximeters and the like, as well as in cerebral oximeters, *i.e.*, the sensors are thrown away after a single use. This of course introduces a significant cost factor, and with the increasing emphasis on cost reduction in medical procedures there is a corresponding emphasis on the design and manufacture of equipment which is more economical to produce and correspondingly less wasteful when discarded after only a single use. At the same time, there is also an increased emphasis on the design and manufacture of better and more capable as well as more reliable componentry, which is usually contradictory to the economy paradigm.

SUMMARY OF THE INVENTION

The present invention satisfies both of the above-stated objectives by the provision of an improved spectrophotometric sensor which is particularly (but not necessarily exclusively) useful in cerebral oximetry. In satisfying these dual objectives of economy and performance, the improved sensor provided herewith comprises a less expensive but equally or even more reliable device, which is lighter in weight than predecessor devices yet nonetheless produces the same high level of operating efficiency and accuracy possessed by previous such devices; in fact, the present invention provides improvements in both such areas due to the novel and highly effective structure and method of manufacture made possible by and in accordance with the invention.

More particularly, the present invention provides an optimally small and lightweight spectrophotometric sensor which incorporates a flex circuit having surface-mounted electro-optical components that are electrically coupled to conductive traces carried on the flex circuit, wherein at least some such components have an integrally attached rigid and opaque light passage-defining structure which may comprise a collar-like member preferably a molded element that is "overmolded" upon the electro-optical component. In this aspect, the invention provides a spectrophotometric sensor of the type just noted having an electro-optical component which is embedded in a generally rigid and opaque light-passage structure comprising an aperture that is formed in place

upon the embedded electro-optical component. Preferably, the conductive traces of the flex circuit are connected to short electrical leads extending outwardly from the sensor for only a brief distance and terminated there by a manually connectable and disconnectable connector member.

Furthermore, the invention provides a method of conducting spectrophotometric procedures by use of an electro-optical sensor and a signal processing unit, in which the sensor is applied to the test subject and electrically connected to the processing unit by a coupling carried by and located close to the sensor, said coupling being releasably connectable to a reusable high-quality electrical cable having conductors extending to and connected to the processing unit, to reduce sensor cost, weight, and motion artifact effects. Also provided is a method of manufacturing a spectrophotometric sensor by automated machine operation, including the steps of using a thin flexible substrate which carries thin conductive traces on at least one side, placing electro-optical components in precise predetermined positions on said substrate by using robotic apparatus, and establishing secure electrical connections between said components and said conductive traces by automated means, *e.g.*, by conveying the substrate and placed components through a solder reflow oven, and by using conductive adhesive between said traces and said components.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view showing the basic appearance and nature of a preferred embodiment of the invention;

Fig. 2 is an exploded perspective view showing the components making up the structure of Fig. 1;

Fig. 3 is an overhead plan view showing some of the assembled components of the sensor in place, with others removed;

Fig. 4 is an overhead plan view showing one preferred embodiment of the flex circuit used in the sensor;

Fig. 5 is an overhead plan view showing the main body component of the sensor alone, prior to assembly;

Fig. 6 is an enlarged side elevational view showing a preferred embodiment of the flex circuit and assembled components;

Fig. 7 is a longitudinal central sectional view of the assembled sensor;

Fig. 8 is an enlarged fragmentary sectional view of the portion circled in Fig. 7 and label "VIII";

Fig. 9 is a enlarged perspective view showing a preferred embodiment of an electro-optical component as utilized in the sensor;

Fig. 10 is a further enlarged cross-sectional side elevation taken along the plane X-X of Fig. 9; and

Fig. 11 is a further enlarged cross-sectional side elevation taken along the plane XI-XI of Fig. 9.

DESCRIPTION OF PREFERRED EMBODIMENTS

The basic appearance and nature of a preferred embodiment 10 of the invention is illustrated in an overall manner in Fig. 1 and in further detail in Figs. 2, 7, and 8, from which it will be seen that this preferred embodiment is a composite device comprising a plurality of superimposed layers which are stacked one upon the other and adhesively or otherwise secured together into a composite, laminated structure. As best illustrated in Figs. 1 and 2, the sensor 10 preferably has an overall shape analogous to a "figure 8" or "snowman," having a first, smaller rounded portion 20 at one end and a second, larger rounded portion 22 at the other end, with a narrow waist portion 24 therebetween. A flat "flex circuit" 26 which protrudes from the larger end 22 carries a plurality of electrical traces (noted further below) that are terminated by an electrical connector 28 of a generally conventional nature, by which the sensor 10 may be connected to and disconnected from a spectrophotometric device such as an oximeter, by means of an electrical cable extending therefrom and having a corresponding and cooperating plug or other such connector part at its end (not specifically illustrated).

As illustrated in Figs. 2, 7, and 8 the various layers making up sensor 10 include a principal body portion 12, which preferably comprises a softly resilient but firm molded foam member having certain transverse apertures 56, recesses 58, and other shaped configurations, and preferably made of a conductive polymeric material such as polyethylene. In a specific preferred embodiment, body 12 may be approximately one-tenth to two-tenths inches thick at its thickest point. Immediately atop the main body portion 12 is a layer of adhesive (or thin "double-sided" adhesive tape film) 13, and a shielding layer 14, which preferably comprises copper-impregnated ripstop nylon approximately .005-.010 inches thick, both of which have substantially the same arrangement of apertures and recesses as those formed in the adjacent side of the foam

body 12 so as to register directly therewith when the adhesive layer 13 and shielding layer 14 are in place upon body 12. Atop the shielding layer 14 is the aforementioned flex circuit 26, whose surface-mounted electo-optical components fit closely inside the aforementioned registering apertures in the shielding layer 14, adhesive layer 13 and main body 12. Over the entire upper surface of main body 12, and covering it as well as shielding layer 14 and the flex circuit 26, is a relatively thin outer cover layer 16, which is preferably of polymeric foam or the like, preferably opaque or substantially opaque, and preferably adhesively secured in place on body 12 to hold the component layers under it securely together as well as provide a finished appearance. Fig. 3 is a top plan view of this layered structure with cover layer 16 removed, showing flex circuit 26 in place atop shielding layer 14 (which covers adhesive layer 13).

On the opposite side of the body 12 from the component layers noted above is one or more layers of electrically conductive adhesive 18a (Figs. 2, 7, and 8) and, directly adjacent and upon that, a protective outer liner layer 18b which should have a readily releasable surface characteristic, *e.g.*, silicone-coated polymeric sheet, so that it may be easily and quickly removed from the adhesive layer 18a for use of the sensor 10 by adhesively securing the latter to the forehead or other selected surface area of the patient or test subject by means of the conductive adhesive 18a. Adhesive layer(s) 18a may advantageously be conductive PSA such as "Arclad 8006," by Adhesives Research, Inc.

The overall nature and certain details or features of the flex circuit 26 are best seen in Figs. 4 and 6. Basically, this component comprises a flexible substrate 30 which carries a plurality of electrically conductive traces 32, a light-emitter component grouping 34, light-detectors 36 (preferably, at least two, carried at different spacings from the emitter 34), a programmed calibration memory chip 38, and the aforementioned connector 28. More particularly considered, the flexible substrate 30 preferably includes, in addition to the traces 32, a plurality of additional layers 40, 42, and 44 superimposed over one another on each side of the substrate. These layers may be and preferably are very thin (on the order of one mil thick each) coatings which are screen-printed or otherwise applied atop one another. The layers 40 applied directly to each side of the flexible substrate 30 (and atop the conductive traces 32) are of a non-conductive, electrically insulative material, and they are also preferably of an opaque white coloration, so as to be optically shielding as well as electrically insulative. The

layers 42 applied atop the insulating layers 40 preferably comprise screen-printed conductive silver or the like, to function as an electromagnetic shield, and the outer layers 44, applied over the shielding layers 42, preferably comprise another insulating layer of non-conductive, opaque white material.

In what is at least one of the most preferred embodiments, the flexible substrate 30 may comprise the polyimide sheet material known commercially as "Kapton®" (trademark of Dupont Company), on the order of about .005 -- .015 inches thick in this embodiment; however, other synthetic sheet materials may also be utilized, including more flexible materials such as polyester compounds (including the polyester derivative known as "PEN" (Pentech), which will withstand higher temperatures than many other polyesters), such materials all being electrically non-conductive. The conductive traces 32 applied on at least one side of substrate 30 are preferably copper in the case of Kapton® substrates, (which are somewhat stronger and more heavy-duty than the polyesters), on the order of .0003 inches thick, and covered by tin plate in exposed areas. Particularly located open (uncoated) "window" areas are left in the insulating and conductive shielding layers 40, 42, and 44 in the immediate area where the emitters 34, detectors 36, and memory chip 38 are to be located, to permit the desired electrical connections to be made between the terminals 48 of the components 34, 36, and 38 and the conductive traces 32.

Where the sensor configuration described above is utilized, these electrical connections may be made by silk-screening or otherwise applying solder paste to the specific area on the traces 32 where each such connection is to be made, placing the components 34, 36, 38 precisely in the desired position (by "pick and place", automated robotic apparatus) and using a contact adhesive to temporarily hold the components in this desired placement while the substrate 30 and attached components are conveyed through an oven that is sufficiently hot to melt the solder paste and establish the desired electrical connection without damaging the components, conductive strips or substrate (*i.e.*, about 175°C or less). Where other less rugged materials are used for the substrate 30 (such as polyester), this manufacturing method may be too demanding, but the conductive traces 32 may then be of silver or other conductive ink, printed in place, and the connections between these printed traces and the component terminals may be accomplished by use of conductive adhesives, thereby avoiding the use of hot solder reflow ovens and the like.

The components referred to above as the "emitter" 34 and "detectors" 36 are shown in more detail in Figs. 8, 9, and 10, as well as in Fig. 6, which illustrates the same mounted upon the substrate 30. As noted above, the emitter 34 comprises a selected grouping of wavelength-specific light-emitting components such as LEDs, and the detectors 36 comprise light-sensors such as photodiodes, which provide an electrical output whose magnitude is representative of the light intensity received by them on a real-time basis. In and of themselves, such electro-optical components (now often referred to as "optodes") are very small cubically-shaped solid-state components (indicated at 46 in Fig. 10), with laterally extending electrical terminals 48 protruding therefrom. In accordance with the present invention, each of the electro-optical components 46 is initially encapsulated in a clear epoxy which is preferably applied by the process known as transfer molding, at temperatures of about 150°C or less (to protect the components), to protectively cover each electro-optical component and seal it from moisture, *etc.*, with the electrical connection terminals 48 extending outwardly from the encapsulated component. (The electro-optical component 46 may be supplied in a form by which the component itself is mounted on a metal "lead frame" having integral strip-like projections which form the terminals 48, in which event the component and lead frame are both encapsulated except for the terminals.)

The epoxy-embedded optode 46 thus forms a protected assembly 50 which lends itself well to mechanical handling and other assembly techniques. In accordance with the invention, assembly 50 is overmolded to provide a rigid, windowed outer portion 52 (Fig. 10), for example by using the synthetic compound known as "GE/Ultem" no. 1000F-7101 (available from General Electric Corporation) or other opaque plastic which should be moldable at a sufficiently low temperature to avoid damage to the optode and its embedding material and also capable of withstanding the aforementioned subsequent solder reflow process without damage. Thus, the overmolded component assembly 50, 52 is the actual component which is mounted in place upon the flexible substrate 30 in the particular preferred embodiment under discussion, and it lends itself well to this process due to its size and regulated shape as well as its capability off being handled without damage by mechanical means. The overmolded exterior 52 is preferably opaque and essentially rigid, and it has a window-like opening on one side defined by walls 54, through which light may pass to or from the electro-optical component 46.

The window walls 54 of overmolded cover 52 provide an essentially non-distortable light passage of uniform and consistent shape and dimensions which is not subject to deformation or other such shape changes during use of the sensor, as for example when the sensor is applied to the patient or test subject and pressed firmly into place in a manner which bends or compresses portions of the compliant foam body 12. Also, the walls 54 block ambient light from reaching the sensors, particularly where their outer ends lie in direct contact with the subject to be tested, and the overmolded assembly lends itself well to the automated pick and place manufacturing procedure referred to above, which involves robotic machinery whose use contributes significantly to accurate and consistent component placement at reduced cost. Of course, the bottom extremity of the overmolded electro-optical assembly is the surface applied to the flexible substrate 30 and which carries the adhesive which secures the component in place for soldering, and the connection terminals 48 are offset and configured so that their end extremities basically lie in the same plane as the bottom of the overmolding 52, which is directly adjacent and contiguous to, and substantially the same plane as that occupied by the conductive traces 32, on which the solder paste mentioned previously is applied. It should be pointed out that (as shown in Figs. 9, 10, and 11) the window 54 defined by the overmolding 52 preferably corresponds to and has the same shape as those formed by the molded light guides and optode receptacles disclosed in Applicant's prior U.S. Patent No. 5,465,714, to provide the benefits described therein and broadly disclosed in Applicant's U.S. Patent No. 5,584,296.

Fig. 6 illustrates the assembly produced by mounting the overmolded electro-optical units 34, 36 on the flexible substrate 30, as discussed above, and also shows the calibration memory chip 38 mounted on substrate 30 in essentially this same manner. That is, while memory chip 38 does not necessarily embody the embedded or overmolded structures discussed above in connection with Figs. 9, 10, and 11, it does have projecting electrical terminals which are soldered (or otherwise connected) to the conductive traces 32 in the same manner. It should be noted that, in accordance with the most preferred embodiment of the invention, the mounted and soldered components 34, 36, and 38 are preferably "potted" after they have been so mounted, by applying a small quantity (*e.g.*, a drop or two) of silicone adhesive or the like around at least their edges, to settle around and cover at least side portions of each such component and in particular its soldered or otherwise connected electrical terminals, to thereby further protect them

from undesired direct contact with external objects, and seal them from moisture, dirt, *etc*. This final potting step will or may cover the entire memory chip 38 (as seen at 64 in Fig. 6), as well as the perimeter of the "window" openings left in the shielding and insulating layers 40, 42, and 44, mentioned above, which are provided for the purpose of mounting the electro-optical components. As shown in Fig. 8, the adhesive layer 13 may have somewhat smaller apertures for the components 34, 36, and 38 than the shielding layer 14 and body 12, such that the edges of the adhesive (which may be a thin film) overlie the ends of terminals 48 connected to the traces 32 on the substrate 26 (or overlie the potting compound 64).

It should be pointed out that the calibration chip 38 preferably comprises a miniaturized digital read-only memory device that is programmed at the factory in accordance with the overall performance parameters of the particular optodes used on a given substrate, *i.e.*, the detection response of the particular detectors involved in relation to the particular light emissions produced by the particular emitters (LEDs) being used, regardless of whatever the actual output wavelength of the latter may be (actual center wavelengths of LEDs and the like being subject to a certain amount of variance even though generally within a specified band, and affecting the wavelength-related measurement performance during spectrophotometric procedures). In this manner, the actual performance characteristics of each individual sensor may be instantly and automatically "read" from the sensor by the spectrophotometric device upon being connected thereto, and appropriate calibration of the device for that particular sensor being automatically implemented by the device using its own internal computer or controller.

The completely assembled flex circuit 26, as described above, is placed atop the foam main body 12, with the shielding layer 14 and adhesive layer 13 disposed therebetween, and with the electro-optical components in direct registry with, and disposed within, the corresponding apertures 56 provided in body 12, at which time the memory chip 38 and covered (potted) terminals 48 are preferably received into their corresponding recesses 58 in the foam body 12. This surface configuration of the foam body 12 is illustrated in Fig. 5, in which the openings for the overmolded electro-optical assemblies are designated by the numeral 56 and the recesses for the terminals 48 (as potted, or otherwise) are designated by the numeral 58. As further illustrated in Fig. 5, the top of the main body 12 preferably has a generally flat longitudinal plateau-like

section 60 having the same basic shape as the adhesive layer 13, shielding layer 14 and flex circuit 26, for receiving the latter in flush relationship, and the side portions 62 of main body 12 outboard of plateau area 60 (Figs. 3 and 5) preferably taper downwardly toward the edges of the body, whose flat underside carries the adhesive layer 18a that contacts the skin of the patient/test subject, together with the removable protective outer liner layer 18b.

The narrowed waist portion 24 of main body 12, and the adjacent smaller and larger rounded end portions 20, 22 are provided at least in part in order to reduce the overall size (footprint) of the sensor while nonetheless ensuring optimal shielding of both light and electromagnetic effects for the emitter 34 and detectors 36 and their associated circuitry. In this regard, it should be noted that the conductive body 12 and even the conductive adhesive layer 18a comprise part of the electromagnetic shielding for the sensor, along with the various conductive layers noted above, all of which should be interconnected and coupled to a system ground or other such circuit point (preferably, in accordance with the commonly owned prior patents identified above and incorporated by reference). At the same time, the illustrated sensor configuration also enhances the conformability of sensor 10 to various patient/test subject surface configurations without wrinkling or otherwise distorting the surface of the sensor in the area directly adjacent the patient/test subject, which is an important factor. Of course, the size and shape of the sensor must also be sufficient to ensure reliable adhesion to the forehead of the patient, but this obviously also involves the relative adhesiveness of the substance used in the adhesive layer 18a. Notwithstanding these utilitarian considerations, the "figure 8" or "snowman" shape, as generally illustrated, is also very distinctive and esthetic in appearance, and also helps to differentiate this sensor from all others.

It should be pointed out that there are significant advantages in terminating the electrical conductors for the electro-optical components (*i.e.*, the flex circuit 26 in the preferred embodiment described above) at a point closely adjacent the sensor 10 itself, and using a disconnectable connector at that point to couple the sensor to the spectrophotometric instrument, rather than equipping the sensor with a relatively long length electrical cable or the like whose end extremity carries a plug that is connectable to the instrument itself or some other point intermediate the two. By so doing, the cost of the sensor-connected cable may be eliminated from the cost of each sensor, and perhaps even more importantly the incentive to use inexpensive and hence inefficient

cable for this purpose is eliminated. At the same time, the use of high-grade and relatively expensive cable permanently connected to the oximeter instrument is actually made attractive since it need only be provided once, performs better, and is usable a great many times. In addition, the sensor itself is made lighter in weight and less susceptible to motion artifact, *etc.*, and, the automated and hence less expensive manufacture of the sensor is facilitated, since the practice of using lengthy connection cable attached permanently to the sensor required a manual soldering operation at the point of attachment. At the same time, use of a flex circuit such as that described above not only facilitates automated sensor manufacture but also eliminates other hand wiring, soldering, *etc.* No doubt, other significant advantages will be perceived by those skilled in the art upon further consideration of the foregoing specification.

It should be understood that the foregoing disclosure and attached drawings are directed to one or more particular preferred embodiments of the invention for purposes of illustration, and that variations and modifications of such particular embodiments may well occur to those skilled in the art after considering this disclosure. All such variations *etc.*, should therefore be considered an integral part of the underlying invention, especially in regard to particular shapes, configurations, component choices and variations in structural and system features.

The invention claimed is:

1. A compact, lightweight and flexible spectrophotometric sensor for clinical applications comprising:

a flexible body which is compliantly comformable to the shape of a subject to be examined;

a thin and flexible substrate mounted on said body, said substrate having electrically conductive traces on at least portions of a surface;

a plurality of electro-optical components mounted on said substrate and electrically coupled to said conductive traces, said components including at least one light source and at least one light detector;

said light source and said light detector components each having at least one side and an integrally attached generally opaque member having a generally annular collar-like portion on at least said side thereof to provide a light-guiding passage to and from said side, said generally opaque members and their respective electro-optical components each comprising an integral assembly adapted to facilitate robotic handling and precise placement thereof upon said substrate.

2. A spectrophotometric sensor as set forth in claim 1, wherein said light source and light detector components further include an optically clear light-transmissive covering on at least said side thereof.

3. A spectrophotometric sensor as set forth in claim 2, wherein said collar-like portion is disposed over said light-transmissive covering.

4. A spectrophotometric sensor as set forth in claim 1, wherein said collar-like portion comprises an overmolded structure which is molded in place on said electro-optical components.

5. A spectrophotometric sensor as set forth in claim 4, wherein said light source and light detector components further include an optically clear light-transmissive covering on at least said side thereof.

6. A spectrophotometric sensor as set forth in claim 5, wherein said collar-like portion is disposed over said light-transmissive covering.

7. A spectrophotometric sensor as set forth in claim 1, further including at least one shielding layer disposed between said substrate and said body.

8. A spectrophotometric sensor as set forth in claim 7, wherein said at least one shielding layer comprises a metal-carrying fabric.

9. A spectrophotometric sensor as set forth in claim 8, wherein said at least one layer comprises a metal-impregnated fabric.

10. A spectrophotometric sensor as set forth in claim 2, wherein said light-transmissive covering substantially encapsulates its related component.

11. A spectrophotometric sensor as set forth in claim 4, wherein said over-molded structure substantially encapsulates the component on which it is formed.

12. A spectrophotometric sensor as set forth in claim 11, wherein said overmolded structure is disposed over the light-transmissive covering on the associated component.

13. A spectrophotometric sensor as set forth in claim 1, wherein said body has a thickness greater than that of said integral assembly comprising an electro-optical component and it associated generally opaque member, and wherein said body has a recess for receiving each of said integral assemblies.

14. A spectrophotometric sensor as set forth in claim 13, wherein said body recesses comprise passages extending through said body and opening outwardly thereof through each of two opposite sides, whereby said integral assemblies are receivable into said passages from a first of said sides and face toward the passage opening on the other of said sides, to send or receive light therethrough.

15. A spectrophotometric sensor as set forth in claim 14, further including at least one shielding layer disposed between said substrate and said body, said shielding layer having an aperture therethrough positioned to register with said body recesses and sized to receive and pass said integral assemblies therethrough.

16. A spectrophotometric sensor as set forth in claim 15, wherein said electrically conductive traces are located on a side surface of said substrate and said side is disposed adjacent said body and said shielding layer is disposed between said side surface and a surface of said body.

17. A compact, lightweight and flexible spectrophotometric sensor for clinical applications comprising:

a flexible body which is compliantly comformable to the shape of a subject to be examined;

a thin and flexible substrate mounted on said body, said substrate having electrically conductive traces on at least portions of a surface;

a plurality of electro-optical components mounted on said substrate and electrically coupled to said conductive traces, said components including at least one light source and at least one light detector;

said substrate and said electrically conductive traces extending outwardly of said body only a short distance and terminating at an electrical connector;

said connector having a plurality of separate electrical terminals and certain of said traces being electrically coupled to certain of said terminals;

whereby said electro-optical components on said substrate are electrically connectable to a clinical device located at a distance from the sensor by means of a reusable intermediate cable connected to said clinical device and single use of said sensor results in minimal economic loss.

18. A spectrophotometric sensor as set forth in claim 17, wherein said short distance comprises only a few inches.

19. A compact, lightweight and flexible spectrophotometric sensor for clinical applications comprising:

a flexible body which is compliantly comformable to the shape of a subject to be examined;

a thin and flexible substrate mounted on said body, said substrate having electrically conductive traces on at least portions of a surface;

a plurality of electro-optical components mounted on said substrate and electrically coupled to said conductive traces, said components including at least one light source and at least one light detector;

said body having an overall shape which is thin when viewed from the side or end and which is rounded on the ends and narrows into a necked-down region between said ends when viewed in plan, said substrate extending across said necked-down region and into each of a first and second area located on opposite sides of said region, said at least one light source being disposed at said first area of said body located on one side of said necked-down region and said at least one light detector being disposed at said second area of said body located on the other side of said necked-down region.

20. A spectrophotometric sensor as set forth in claim 19, wherein both said first and said second areas of said body are rounded over most of their surface when viewed in plan.

21. A spectrophotometric sensor as set forth in claim 21, wherein each of said rounded ends of said body are substantially wider than said substrate.

22. A compact, lightweight and flexible spectrophotometric sensor for clinical applications comprising:

a flexible body which is compliantly comformable to the shape of a subject to be examined;

a thin and flexible substrate mounted on said body, said substrate having electrically conductive traces on at least portions of a surface;

a plurality of electro-optical components mounted on said substrate and electrically coupled to said conductive traces, said components including at least one light source and at least one light detector;

a data memory chip mounted on said substrate and having electrical terminals connected to said conductive traces thereon, to store and read out data representative of

the overall intensity response of the particular light detector mounted on said substrate to light from the particular light source mounted thereon, thereby facilitating calibration of a clinical analytic device coupled to said sensor for operation therewith.

23. A spectrophotometric sensor as set forth in claim 22, wherein said memory chip has a protective covering over its exterior.

24. A spectrophotometric sensor as set forth in claim 23, wherein said protective covering extends over the electrical terminals of said memory chip.

25. A spectrophotometric sensor as set forth in claim 24, wherein said memory chip comprises a miniature digital read-only memory.

26. A spectrophotometric sensor as set forth in claim 1, further including a data memory chip mounted on said substrate and having electrical terminals connected to said conductive traces thereon, to store and read out data representative of the overall intensity response of the particular light detector mounted on said substrate to light from the particular light source mounted thereon, thereby facilitating calibration of a clinical analytic device coupled to said sensor for operation therewith.

27. An electro-optical component assembly for use in a spectrophotometric sensor, comprising in combination:

an electrically actuated and optically responsive component to emit or receive light when electrically connected; and

an encasement covering at least the edges and part of an optically responsive side of said component, said encasement defining a light-transmissive path for light impinging upon or emitted from said optically responsive side of said component, and said encasement being formed in place upon said component.

28. An electro-optical component assembly for use in a spectrophotometric sensor as set forth in claim 27, wherein said encasement defines an aperture disposed in alignment with said optically responsive side of said component, said aperture forming at least part of said light transmissive path.

29. An electro-optical component assembly for use in a spectrophotometric sensor as set forth in claim 27, wherein said encasement comprises optically transmissive material which covers at least said edges and said side of said component, said optically transmissive material comprising at least part of said light transmissive path.

30. An electro-optical component assembly for use in a spectrophotometric sensor as set forth in claim 29, wherein said encasement further includes an outer covering extending over the outside of at least portions of said optically transmissive material, said outer cover being generally opaque and defining an aperture disposed in alignment with said optically responsive side of said component, and with said optically transmissive path, said aperture forming an extension of said path.

31. An electro-optical component assembly for use in a spectrophotometric sensor as set forth in claim 30, wherein said outer covering comprising an overmolding which is formed in place upon said component and optically transmissive covering.

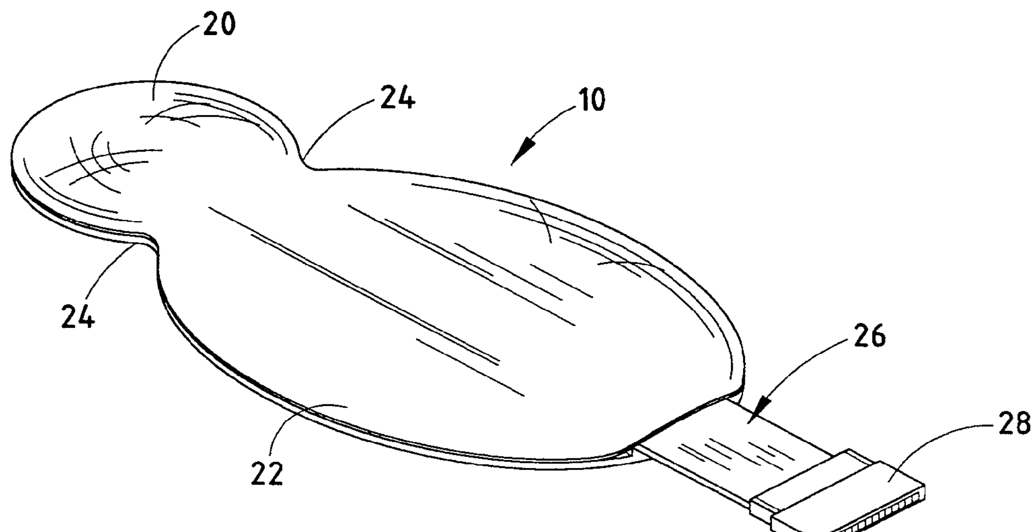

FIG. 1

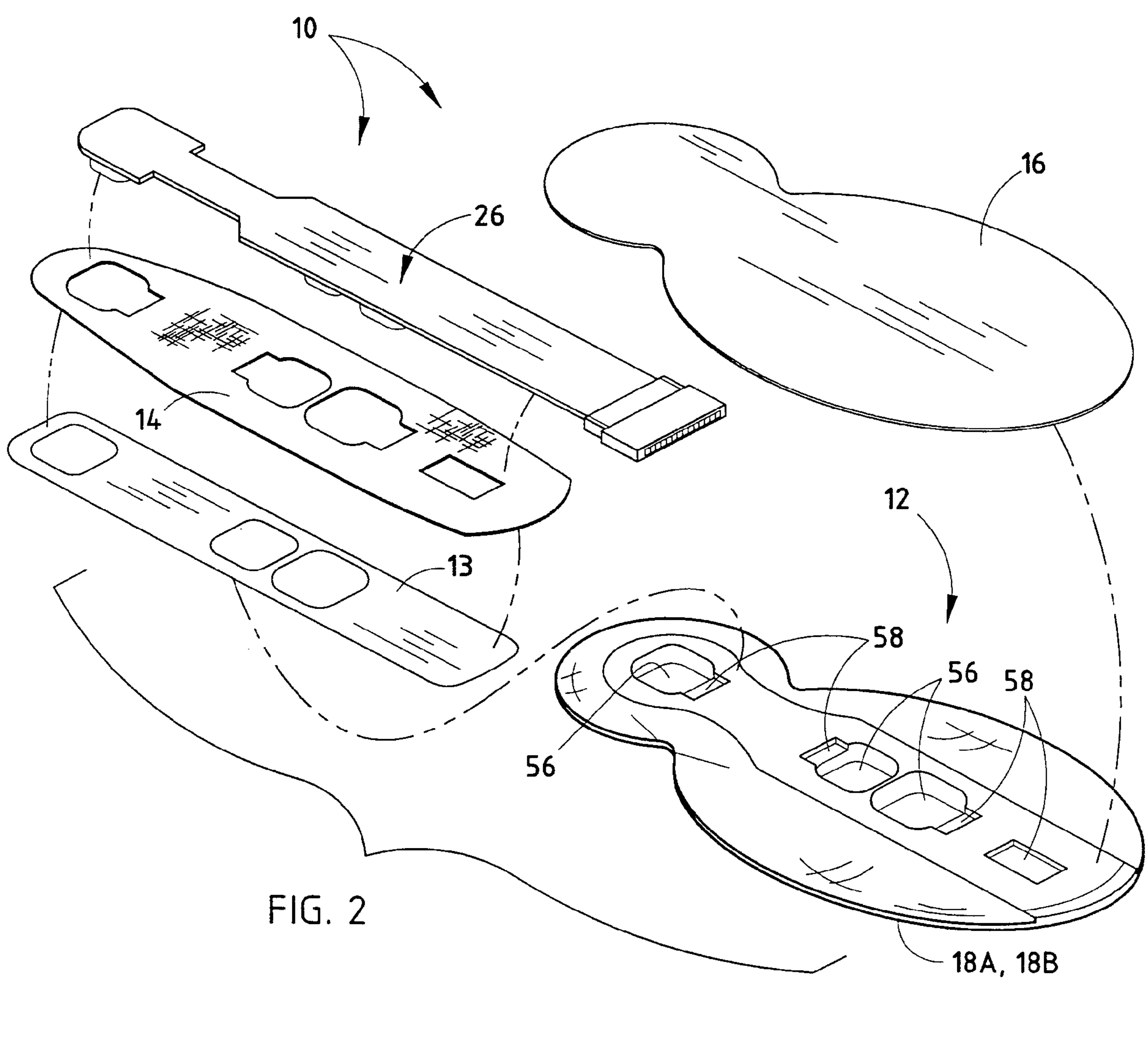

FIG. 2

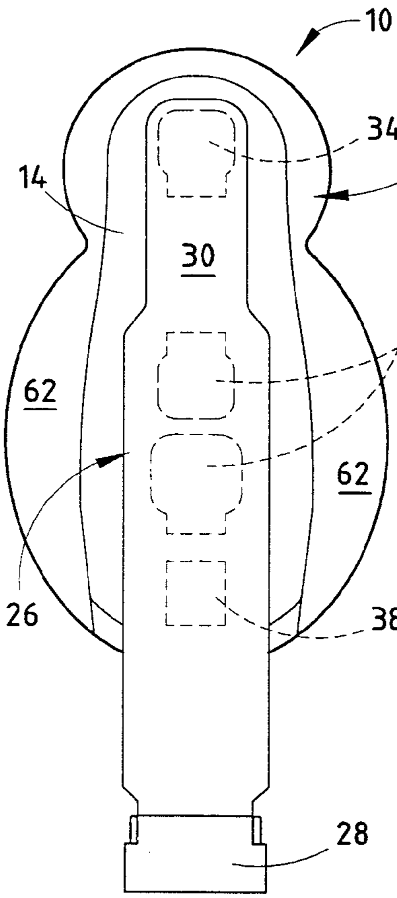

FIG. 3

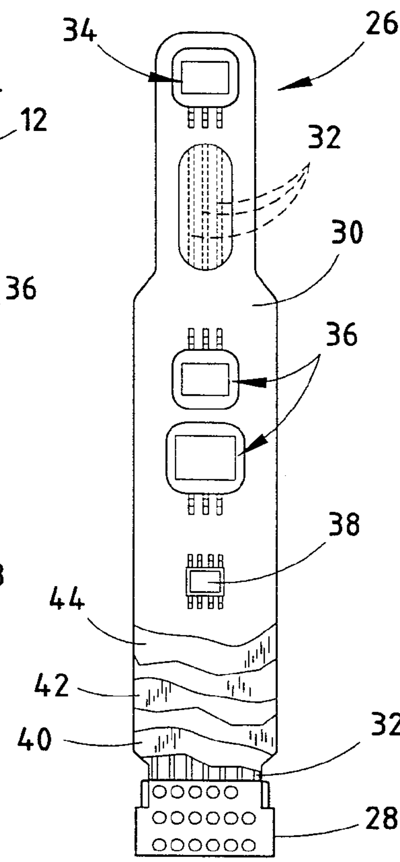

FIG. 4

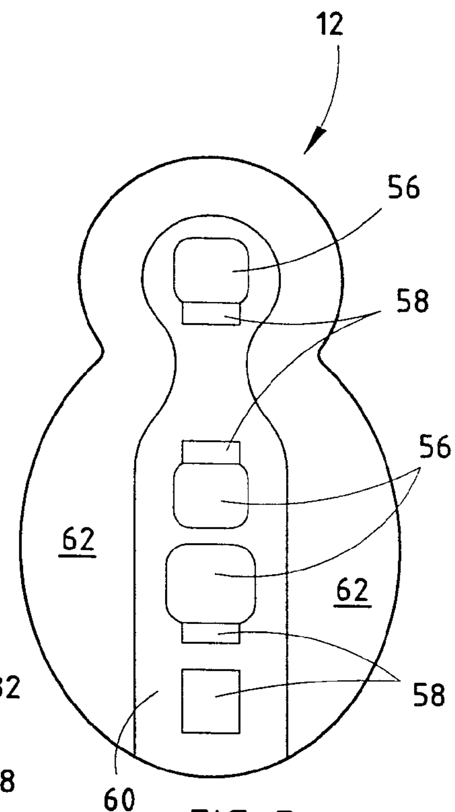

FIG. 5

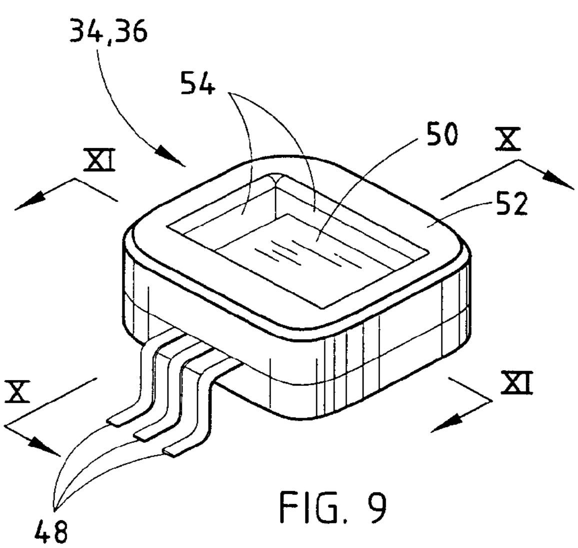

FIG. 9

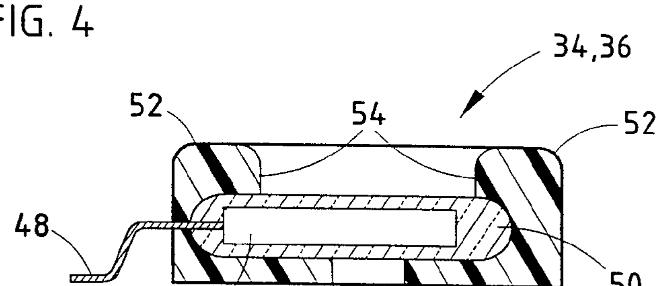

FIG. 10

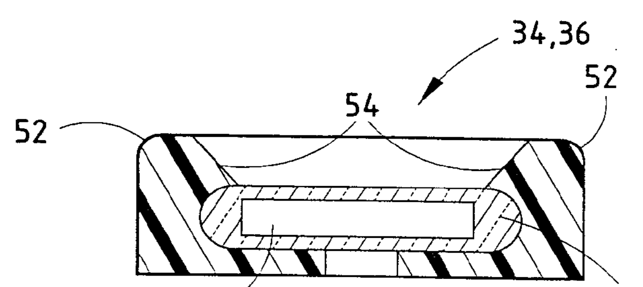

FIG. 11

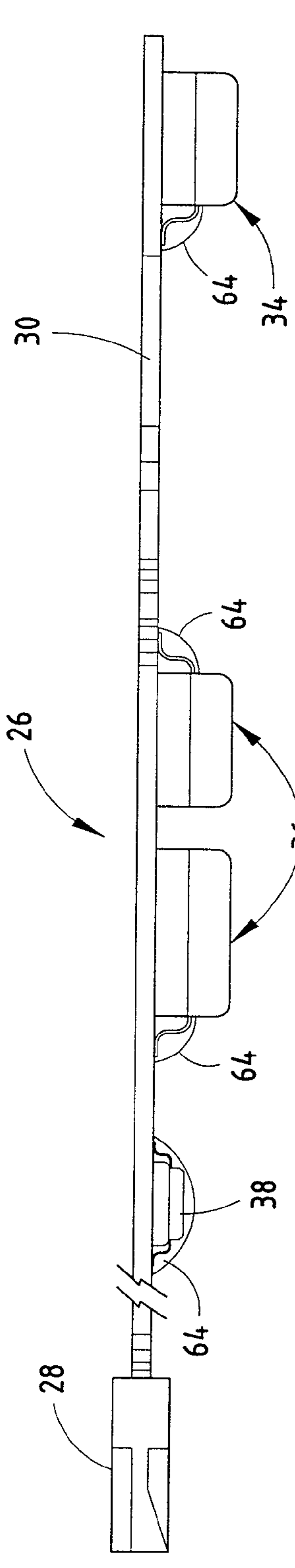
FIG. 6

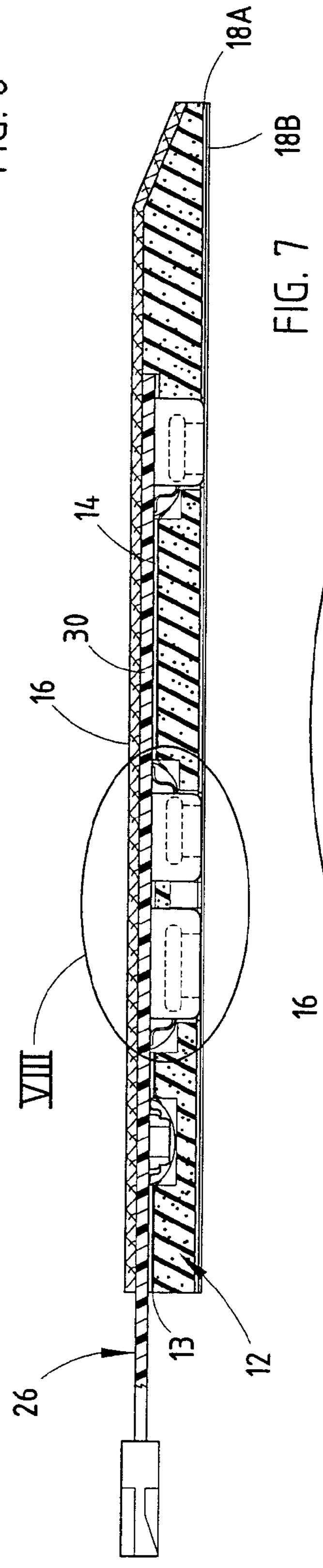
FIG. 7

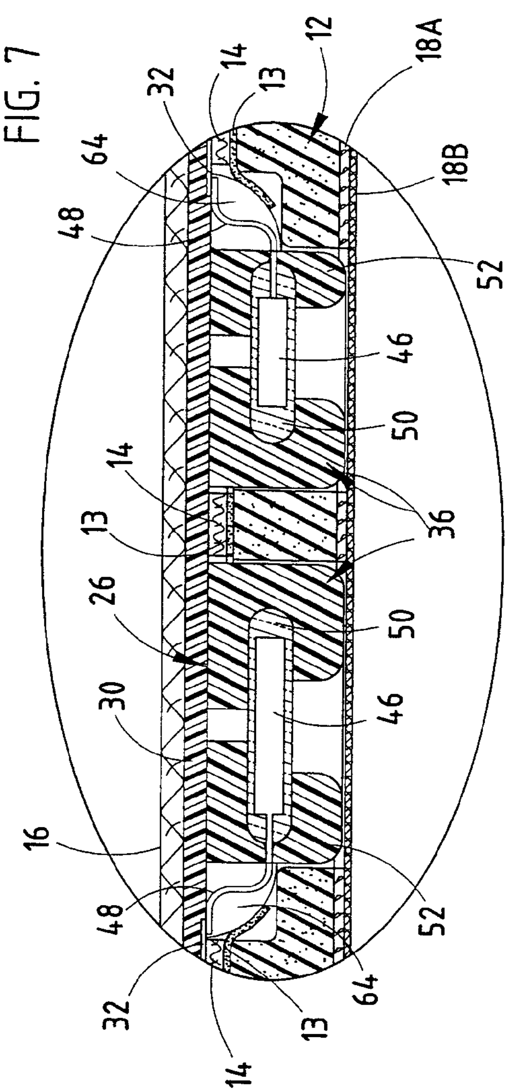
FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/09502

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/00
US CL :600/323, 344
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/310, 322, 323, 340, 344

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,584,296 A (CUI et al.) 17 December 1996, col. 8 line 43 to col. 10 line 61.	1-12 --- 26
X --- Y	US 5,249,576 A (GOLDBERGER et al,) 05 October 1993, entire document.	17-25 --- 26
X	US 5,465,714 A (SCHEUING) 14 November 1995, col. 5 line 56 to col. 6 line 34.	27, 29

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer ERIC F. WINAKUR
Facsimile No. (703) 305-3230	Telephone No. (703) 308-3940